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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/233,218	01/20/1999	CLAIRE A CAJACOB	04983.0025.U	7809

22930 7590 12/17/2001

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/17/2001

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/233,218	CAJACOB ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action responds the Amendment received on October 4, 2001 (Paper No. 18).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 11-21 under 35 U.S.C. § 101 for lacking patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, in the Office Action mailed on July 16, 2001 is maintained for the reasons of record.

Applicants' arguments received on October 4, 2001 have been fully considered but they are not found persuasive.

Applicants argue that the present specification describes many objectives that are met by the present invention, for example, a substantially purified nucleic acid sequence which encodes a glutamyl tRNA reductase (GluTR) or fragment thereof (pp. 2) and that sufficient evidence, by virtue of homology, has been demonstrated. Applicants state that the claimed nucleic acids exhibit varying degrees of homology (all of which are less than 70%) and "generally" (middle paragraph) have a molecular weight of about 270kD among species (pp. 2).

This point is not persuasive because first, the claims are not drawn to a glutamyl tRNA reductase but a nucleic acid sequences comprising the claimed SEQ ID Numbers. Furthermore, the unreliability in assigning proteins' functions strictly based on their degree homology was already set forth in the previous Office Action, clearly shifting burden of proof to the Applicants.

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However, Applicants' response have not set forth any supportive evidence demonstrating that the claimed nucleic acids encode a polypeptide that has the same function as their homologous counterpart (i.e., GluTR). Although the Applicants state that the product of the claimed nucleic acids have a similar molecular weight to that of GluTR, this in no way serves to demonstrate the functionality of the proteins encoded by the claimed nucleic acids.

Applicants also argue that the examiner must accept the asserted utility unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. It is believed that the references set forth in the previous Office Action, demonstrating the unreliability in assigning proteins' functions strictly based on their degree homology, was evidence enough for shifting of the burden. Furthermore, Applicants' argument drawn to the cited references not being drawn to GluTR and thus, not credible references, is also not found persuasive because the references teach the unreliability of the *practice* in assigning proteins' functions strictly based on their degree homology, thus not just limited to the protein of disclosure (emphasis added).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11-21 under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the Office Action mailed on July 16, 2001 is maintained for the reasons of record.

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Applicants' arguments received on October 4, 2001 have been fully considered but they are not found persuasive as already set forth above.

The rejection of claims 1, 2, and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, in the Office Action mailed on July 16, 2001 is maintained for the reasons of record.

Applicants' arguments received on October 4, 2001 have been fully considered but they are not found persuasive as already set forth above.

Applicants argue that the enablement rejection is "inconsistent with the current state of law" (pp. 5) because the law provides that experimentation is not necessarily undue simply because it is complex, if the art typically engages in such experimentation (pp. 5).

This point is not found persuasive because the enablement rejection was not made solely based on the fact that the art was complex. The previous Office Action clearly set forth many conditions that resulted in the undue experimentation determination (see Office Action, pages 4-7). Furthermore, the enablement rejection was made not because a skilled artisan could not make-and-test the invention as claimed (for it is agreed that a skilled artisan could make-and-test whether or not a protein works or not), but because the specification did not demonstrate that the proteins encoded by the claimed nucleic acids had the same function as that of the compared (i.e., GluTR). Absent this evidence, it would require undue experimentation of a skilled artisan to use the claimed nucleic acids to encode/and use as a functional GluTR. The only supporting evidence given by the specification is the percent homology of the claimed nucleic acids to the

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GluTR sequence. The references set forth in the previous Office Action demonstrated the unreliability in assigning proteins' functions strictly based on their degree homology, shifting the burden on the Applicants. To this, Applicants have not provided evidence to the contrary, and therefore, the enablement rejection is maintained.

The rejection of claims 1, 2, and 10-21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, in the Office Action mailed on July 16, 2001 is maintained for the reasons of record.

Applicants' arguments received on October 4, 2001 have been fully considered but they are not found persuasive.

Applicants state that the written description requirement is simply to ensure that the inventors had possession of the claimed subject matter, i.e., to ensure that the inventors actually invented what is claimed. Therefore, Applicants conclude that in accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims and that to contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues (pp. 7).

This point is not found persuasive because the Office Action mailed on February 1, 2001 explicitly cited Vas-Cath v. Mahurkar, 19 USPQ2d 1111, making clear that "applicants must convey with reasonable clarity to those skilled in the art, as of the filing date sought, he or she was in possession of the *invention*" and that the invention, for purposes of the 'written

description inquiry, was “*whatever is now claimed.*” (pp. 5 of the Office Action). As already set forth in the previous Office Action, it was not apparent from the specification that it disclosed the full open reading frame of the claimed nucleic acids. According to the Example 7 of the Written Description Training material, claims to a nucleic acid comprising a SEQ ID Number when the specification does not disclose a full-open reading frame, would read on full-length genes and cDNAs that are not further described (pp. 31, see attached). For example, a cDNA’s principle attribute would include its coding region and a partial cDNA that did not include a disclosure of any open reading frame (ORF) of which it would be a part, would not be representative of the genus of cDNAs because no information regarding the coding capacity of any cDNA molecule would be disclosed (pp. 31), rendering the claims lacking in their written description.

Amending the claims to recite nucleic molecules “consisting of” or demonstrating that the specification discloses a full-open reading frame for each of the claimed nucleic acids would overcome this rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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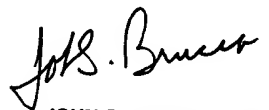
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

12/12/01



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER